Summarizing and Reporting Data A Proposed Framework

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Topics

- Vision and purpose of report
- Overview of report outline
- Potential sources of information
- Next Steps

Vision of New Report

- A coordinated, interagency (USG) annual report with science-based information about antibiotic drug use and resistance in animal agriculture
- Integrate an array of information on animal demographics, animal health, drug use, and resistance to provide a comprehensive picture of antibiotic use practices in animal agriculture

Purpose of New Report

- These reports will:
  - Enhance transparency regarding antibiotic use practices in food-producing animals
  - Summarize data important for:
    - assessing the adoption of changes outlined in FDA's Guidance 209 and 213
    - gauging the success of stewardship efforts and guiding their continued evolution and optimization

Overview of Report Outline

- Introduction
- Animal Health/Demographic Indicators
- Drug Use Indicators
- Antibiotic Resistance Indicators
- Discussion
- Appendices

Report: Introduction

- Background: include discussion of…
  - interagency process for formulating report
  - significance of resistance to human/animal health,
  - current antibiotic policies/initiatives
  - stewardship initiatives (including industry-sponsored)
  - relevant changes since last reporting period
- Objectives/Purpose
  - Describe/discuss purpose – as outlined in slide 4

Animal Health/Demographic Indicators

- Summarize available data on animal populations and disease incidence to provide context regarding:
  - Changes in animal populations
  - Occurrence of animal disease
- Such factors may influence antibiotic use

Drug Use Indicators

- Summarize data on extent and purpose of antibiotic use in various animal agriculture settings
- Could draw on several types of information including:
  - Sales/distribution data
  - Survey data on antibiotic use
  - other

Antibiotic Resistance Indicators

- Summarize available data on antibiotic resistance among foodborne bacterial pathogens and commensal bacteria including:
  - NARMS data (food and animal sources)
  - Potential on-farm data
  - Other
- Potential inclusion of animal pathogen data

Discussion Section

- In light of information summarized on animal demographics, animal health, drug use, and resistance
  - provide observations regarding antibiotic use practices in various animal agriculture settings
  - discuss resistance in relation to antimicrobial use
  - Identify areas of improvement and areas where further efforts are needed

Discussion Section

Assessing the adoption of changes outlined in FDA's Guidance 209 and 213

Feed/water use of medically important antibiotics are:

- not being used for production purposes
- only being used for legitimate/appropriate therapeutic purposes
- only being used with authorization of licensed veterinarian

Discussion Section

Gauging the success of stewardship efforts and guiding their continued evolution and optimization

– assess extent to which use indicators align with stewardship/responsible use standards and industry best practices, in light of animal demographics and animal health indicators

– identify associations between antibiotic drug use practices and resistance

Discussion Section

Gauging the success of stewardship efforts and guiding their continued evolution and optimization (continued)

– discuss/highlight areas where further efforts may be needed

- informs Federal agencies in terms of policy development, research
- informs industry, academia, veterinary profession

Potential data sources

- Animal demographic information
  - USDA/NASS
- Animal health information
  - Enhance currently collected/summarized
- Drug Use Indicators
  - FDA (sales), USDA (on-farm use)
- Resistance Indicators
  - NARMS (FDA. USDA/FSIS)
  - On-farm (USDA/APHIS)

Potential data sources

- Animal demographic information
  - USDA Ag Statistics Annual Reports
    - Species-specific annual reports
    - Population statistics by animal type, geographic location etc.
    - Slaughter numbers
    - Live weights

Potential data sources

- Animal health information
  - Currently, limited data are available on disease incidence in animals (that may be a driver of antibiotic use)
  - Information on disease occurrence, distribution, key animal health events would be valuable
  - Important for interpreting antimicrobial use data
- Input needed on potential additional sources of this data

Potential data sources

Drug Use Indicators

- National cross-sectional studies
  - Percent of animals in national population receiving antimicrobials by drug class and reason for use
  - Percent of operations in the U.S. using antimicrobials by drug class and reason for use

Potential data sources

Drug Use Indicators

- Longitudinal studies
  - Number of animals receiving antimicrobials by class of antimicrobial and by reason for use
  - Dosage amount
- Other

Potential data sources

- Resistance Indicators
  - On-farm Resistance
  - USDA-NARMS (cecal, HACCP)
  - FDA-NARMS (retail meat)

Potential Data Sources
On-farm Resistance

- Percent of isolates resistant by class of antimicrobial and by organism
  - National cross-sectional studies
  - Longitudinal studies
  - Other (see APHIS AMR Initiatives doc)

Potential Data Sources
USDA-NARMS (cecal, HACCP)

- NARMS Annual Animal Report
  - Percent resistance by bacteria, drug, animal both pre- and post-chill
- NARMS Integrated Report
  - Genetic determinants of resistance (including those for drugs not labeled)
  - Resistance transfer mechanism (plasmid types and mutations)
- Research
  - Metagenomic data for surveillance of the animal antimicrobial resistome

Potential Data Sources
FDA-NARMS

- NARMS Retail Meat Report
  - Percent of resistant isolates by bacteria, drug, food commodity
- NARMS Integrated Report
  - Genetic determinants of resistance (including those for drugs not labeled)
  - Resistance transfer mechanism (plasmid types and mutations)
- Research
  - Metagenomic data for surveillance of the retail antimicrobial resistome

Report: Appendices

- Summary of relevant stewardship principles/standards (government, academia, veterinary, and industry-based)
- Additional information such as references, methods, data, lists of tables/figures, other reports/publications, etc.

Next Steps

- Data collection and reporting
  - Consider comments received today and submitted to the docket
    - Refine plan based on input
  - Will continue to seek public input
  - Goal to collect new on-farm data in 2016
    - Availability of resources a key factor
  - Goal to publish first integrated report in 2018